Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Promoting Telehealth for Low-Income Consumers	)	WC Docket No. 18-213
	)	

REPLY COMMENTS OF OCHSNER HEALTH SYSTEM

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EXECUTIVE SUMMARY

Ochsner is optimistic that the FCC's Pilot program, if it is implemented in a careful but flexible way, will advance innovation in the provision of cost effective care to targeted populations, while making a positive difference in health outcomes to people living with chronic health conditions. The information the FCC will gain from a range of differently structured remote care projects will represent a valuable contribution to informed public policy to encourage the deployment of remote care when it can be an effective adjunct to in-person care.

The comments filed on the FCC's Connected Care Notice nearly uniformly applaud the agency's efforts to encourage health care providers to offer remote care services to low-income and underserved populations with chronic health conditions. Many comments however, suggest that the FCC not replicate existing Universal Service program rules and procedures for Pilot projects, and Ochsner agrees that prescriptive eligibility rules and procedures will discourage participation in the Pilot by the very health care providers that have the most experience with telehealth projects.

The FCC should carefully coordinate its program with those of other federal and state agencies that subsidize health services to low-income or underserved populations so that its procedures and funding mesh or are not inconsistent with other programs. At this Pilot stage, the FCC should welcome reasonable experimentation in remote care projects. In order to learn as much as it can and then act on informed knowledge, the FCC should apply flexible guidelines for this Pilot program to encourage reasonable experimentation with a range of structures so that the agency has the data to evaluate results.

Many commenters recommended that the FCC not limit Pilot funding to a discount on competitively bid broadband connections, as diagnostic devices, apps, and program costs may be

more significant cost drivers in remote care programs. Ochsner agrees with these recommendations. Ochsner does not purchase broadband connectivity for its remote care programs, so providing a discount for something that is not a cost to Ochsner provides no incentive to participate in the Pilot. The FCC should not risk losing healthcare providers with significant telehealth experience by adopting such a narrow subsidy.

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Ochsner Health System ("Ochsner") filed extensive comments in response to the Federal Communications Commission's (the "FCC")'s Notice of Proposed Rulemaking proposing the establishment of a Connected Care Pilot program.[1] The comments filed demonstrate that there is nearly universal support for establishing a trial to provide the FCC and health-related federal agencies with actionable information on the barriers to broader deployment of connected care to underserved and low-income populations. Nevertheless, many commenters raised legitimate concerns about aspects of the FCC's proposed framework for the Pilot. Ochsner submits Reply Comments to underscore how many of the expressed concerns and recommendations should inform modifications to the FCC's framework so that the Pilot can achieve all the FCC's stated goals.

I. A "One Size Fits All" Pilot Program Will Fail to Achieve the FCC's Stated Goals.

Ochsner's Comments explained its "out of facility" patient-centered connected care programs rely upon the patient's already existing broadband service contracts with wireless providers and the patients' own tablet or smartphone.[2] This arrangement allows Ochsner to

[1] *See* Promoting Telehealth for Low-Income Consumers, *Notice of Proposed Rulemaking*, 34 FCC Rcd. 5620 (2019) (hereafter *Connected Care Notice*).

[2] *See* Comments of Ochsner Health System at 4-8. The patient's end user device, with the use of an app, can synch with diagnostic or medical devices provided to the patient and used in the field to transmit health data to Ochsner.

concentrate on providing the necessary elements of remote patient monitoring and care directly, without putting Ochsner in the position of selecting a broadband provider. Ochsner's experience has been that patients will more readily participate in, persist in participation and have better health outcomes simply by using their own pre-existing broadband connections to transmit data or interact via video with a Health Care Provider ("HCP"). This has proven to be a highly effective care structure, one with no intermediaries. It greatly simplifies the patient enrollment process and boosts participation, which in turn has led to higher patient adoption and use rates.

Ochsner does not claim to have the only viable remote care program structure and while Ochsner is a leader in this area, there are other remote care programs it can envision offering if outside support were to be available. Many organizations filing comments have accomplished significant work in providing remote health offerings and they are not all alike. Ochsner strongly supports those commenters that suggest that the FCC would learn more and thus benefit from being somewhat flexible in allowing experimentation within the Pilot program.[3] And the FCC has the ability to fund reasonable experimentation in a Pilot to learn what makes remote health care feasible on a larger scale. This means a Pilot could reasonably support more of the costs of remote services that are not otherwise covered, including some portion of the cost of the medical devices provided to patients for remote monitoring purposes and the apps that make them useful.

Moreover, as a number of commenters observed, the FCC could reasonably allow parties that are not strictly HCPs to participate or have some aspect of their activities funded in a Pilot program if they propose to address underserved communities or targeted health conditions in a manner that will inform good public policy by adding to the FCC's knowledge base.

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[3] *See generally* Comments of American Physical Therapy Association; Comments of American Urological Association; Comments of Medical University of South Carolina and Palmetto Care Connections; Comments of the State of Colorado; Comments of Virginia Telehealth Network.

The comment record reflects that HCPs with remote health care programs currently structure these programs differently. This means a one size fits all approach to a Pilot, particularly one that subsidizes only a single broadband connection procurement structure, will inevitably disadvantage those that use other structures, or heavily discourage their participation. That would represent a huge loss to the FCC in terms of achieving its goal to seek to understand how to replicate promising, innovative approaches to remote care to low-income or underserved populations. As Ochsner and others demonstrated in comments, the FCC is not required by law to fund only competitively bid broadband connection services.[4] It also need not reuse structures created for different Rural Health care program purposes for its Pilot when they are demonstrably ill-suited, and needlessly cumbersome and complex for a Pilot.

The FCC can police the potential for fraud waste and abuse in a Pilot by requiring applicants that are selected and awarded funding to certify as to the use of the funds provided. As suggested by the comments of the State of Colorado, the FCC can build upon the Center for Medicare and Medicaid Services' ("CMS") existing program reporting requirements to enhance efforts to guard against fraud, waste, and abuse while reducing regulatory burdens on selected applicants who in fact may be already subject to CMS regulatory regimes.[5] The FCC's current proposal to limit offering of connected services for only healthcare-related purpose adds an extra

[4] *See* Comments of Ochsner Health System at 22-27.

[5] Comments of the State of Colorado at 4, 7-8 (discussing CMS' "strict rules and regulations for applications and reporting requirements including detailed outcomes, measurements, work plans, ongoing reporting of costs and quality measures, and evaluations" as well as requirement for "periodic discussion with CMS officials on program operations, lessons-learned, midcourse corrections (where needed), and final evaluations," which can all be used to help the FCC guard against fraud, waste, and abuse while not substantially increasing participating projects' regulatory burden during a Pilot program).

layer of protection against fraud, waste, and abuse.[6] As Ochsner previously pointed out in its Comment, while the potential for fraud, waste, and abuse is a legitimate concern, setting overly prescriptive structures for a Pilot will add little to protection against fraudulent use, while simultaneously stifling innovation that could benefit the FCC in achieving its stated goals for a Pilot.[7]

Pilots should be somewhat flexible in allowing for more than a single structure for funding aspects of the costs of providing care or the FCC risks missing important information that could mean the difference between getting a balanced view and not studying a range of options to address an identified challenge. Pilots should encourage responsible experimentation, and program applicants should be selected for funding based on the FCC's judgement that the applicant's capability and proposed approach will add to the body of knowledge about how best to encourage cost effective programs with positive health outcomes for patients and the system as a whole.[8] This can be accomplished by assessing health outcomes, patient and provider utilization, return on investment, and cost-effectiveness from the perspective of patients, payers, and providers.[9] Specifically, service eligibility for funding should be based on whether the services are "reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice," rather than applying prescriptive

[6] *See* Comments of Virginia Telehealth Network at 10.

[7] *See* Comments of American Urological Association at 8.

[8] *See* Comments of American Physical Therapy Association at 4 ("APTA recommends that FCC, in evaluation applications, not look merely to the cost of a project and the conditions it treats, but also whether the project will use telehealth in innovative, new ways.")

[9] *See* Comments of Medical University of South Carolina and Palmetto Care Connections at 7, 9.

criteria limiting applicant proposals to specific conditions, specific demographics, specific medical procedures, or specific care delivery method.[10]

The proposal in the Connected Care Notice to limit Pilot participation only to HCPs may fail to capture critical input from innovative, sophisticated care providers and entities who may be able to access underserved communities and that can deliver cost-effective care to those with chronic health conditions.[11] Ochsner supports the view expressed by many other commenters that the FCC's past USF programs have eligibility criteria that may be too strict for the purposes of this Pilot.[12] Determining Emergency Room doctors or Emergency Medical Technicians are not eligible for the Pilot, for example, risks losing their insights into making remote health care delivery better and more innovative. Application of strict definitions that may serve important purposes in other contexts, if used in this one, will limit the Pilot's ability to achieve its goal to explore ways to innovate in the delivery of care. The FCC should seek to provide flexibility and not operate this proposed Pilot as it has other established USF programs.[13]

II. Obstacles to Connected Care

The stated purpose of the FCC's proposal is to determine how cost effectively to reach underserved or low income populations with connected care that can make a positive difference in their health and their lives. As reflected in many of the comments, it would seem to be a wise policy choice for the FCC to coordinate at the outset with the Department of Health and Human

[10] *See* Comments of American Academy of Family Physicians at 2; Comments of Healthcare Leadership Council at 2 (recommending the FCC take a "technology-neutral" approach that allows technologies to be eligible as long as the technology is tied to the type of medical service needed).

[11] *See* Comments of Connected Health Initiative at 8-9; Comments of Doctor on Demand at 2; Comments of Multistakeholder at 2.

[12] *See* Comments of Connected Health Initiative at 8.

[13] *See* Comments of Connected Health Initiative at 8.

Services, with CMS, the Veteran's Administration and other federal agencies that have health related portfolios to ensure that the Pilot framework can feasibly operate consistent with other federal policies and so that Pilot participants do not face new obstacles in providing remote care to targeted patient populations. Without this coordination, the FCC risks wasting Pilot program resources by financially supporting elements of remote care that may not need support. It may also fail to address obstacles that federal or state laws and regulations have – largely unintentionally - put in the path of greater deployment of connected care programs. This careful coordination should be a critical part of the pre-Pilot process.

Many commenters also expressed concern that proposed elements of eligibility, program structure, restrictions on supported services and other aspects of the Pilot program framework risked defeating the purpose of a Pilot. These concerns are well founded. HCPs may be disincentivized from participating in this Pilot if the Pilot does not effectively address the provision of connected care services – such as free or discounted access to HCP-funded end-user equipment or devices – from the risk of being considered a prohibited inducement under the Self-Referral or Anti-Kickback Statutes. As commenters observed, because HCPs have little, if any, flexibility in funding these types of services on their own, this concern calls for funding from federal programs or, at least, a regulatory safe harbor.[14]

Ochsner strongly supports the goals the FCC has articulated for its Pilot; the key to achieving them is to reframe aspects of the proposal so that it takes account of other federal and state laws and regulations so that the Pilot can work for potential program participants, including those that do not dictate how patients receive broadband connectivity. The framework also must

[14] *See* Comments of AdventHealth at 4; Comments of American Hospital Association at 20.

account for and attempt to address the other obstacles to remote care in what is admittedly a very complex healthcare ecosystem.

III. Most Comments View the Scope of Proposed Supported Services as Too Narrow

The Connected Care Notice identified what the FCC believed to be the "dominant modes" for HCPs buying connectivity for connected care and the Notice proposed funding 85% of eligible broadband costs when these connections are sole sourced through a single communications service provider using the Rural Healthcare program forms and general procedures. As Ochsner demonstrated in its Comments, there are existing remote care structures do not require the establishment of a new communications connection to provide care. Ochsner therefore urges the FCC to allow its Pilot program the flexibility to address this and other obstacles to deployment if eligible HCPs have already established broadband connectivity with their patients. It would be extremely counterproductive to require projects to restructure and to spend more money in order to fit with the Rural Healthcare framework, which was designed for a different purpose.

For remote patient monitoring devices, the FCC in its Notice stated that its prior record suggested that these devices generally are single purpose and are designed or configured so that they cannot access the public Internet. This may be true for some, but not all remote health care offerings, as Ochsner demonstrated in its Comment. In fact, mobile application-based connected care services, by using a patient's own device or a medical device connected through a patient's device and their own broadband connection, "offer great promise for scalability."[15] At least eleven commenters in the record supported the inclusion of mobile applications as a supported

[15] *See* Comments of Medical University of South Carolina and Palmetto Care Connections at 5.

service.[16] Similarly, cloud-based access and communication platforms used in remote patient monitoring may only require very limited bandwidth to transmit data for connected care programs.[17] Thus, requiring HCPs to provide patients with standalone single-purpose devices to access these platforms could well result in HCPs incurring disproportionate costs and would waste resources that could have been used to connect many more patients with the platforms using their own devices. As the Comment of Lifeguard Health Networks observed, allowing devices to retain general access to other internet-based services and information could potentially increase the patients' utilization of the technology and incentivize them to remain connected with their provider.[18] This has certainly been the case in Ochsner's remote care programs.

Comments also demonstrated that there is no consensus or any simple means to allocate between or among whatever program support might be made available between supported and non-supported services if these devices are capable of accessing the Internet. As at least two commenters correctly pointed out, distinguishing supported and non-supported services would necessarily require HCPs and any service provider partners to develop or adopt tools to assist in monitoring and tracking traffic, which could be cost-prohibitive, or at least would incur substantial cost not proportionate to additional traffic that might be transmitted over an existing broadband connection within a Pilot project.[19]

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[16] Comments of AdventHealth; American Association of Nurse Practitioners; American Hospital Association; Cascade Comprehensive Care; Hathaway Sycamores; Lifeguard Health Networks; Mercy Virtual; OCHIN; Ochsner Health System; Pharmacy Health Information Technology; and Virginia Telehealth Network.

[17] *See* Comments of Lifeguard Health Networks at 6.

[18] *See* Comments of Lifeguard Health Networks at 7.

[19] *See* Comments of Gila River Telecommunications at 3; Comments of State of Maine at 8-9.

If would-be program participants do not seek or require program support of a broadband connection, then this question about allocating resources between qualifying and non-qualifying uses is moot. For example, if patients use their already existing smartphones and tablets as the means of connection in this Pilot, then they are paying for the broadband service already and there is no reason to try to parse out eligible and ineligible uses for the connection. To the extent the FCC determines that service vouchers to assist with broadband connection costs or similar subsidies should be given to low-income Pilot participants, then Ochsner would suggest that for administrative simplicity in the Pilot, any amount to be subsidized be capped at some discounted level to reflect the mixed use of the smartphone or tablet for healthcare and other connections.

As to whether and how the FCC might assist in funding the other expensive components of connected care, the comments demonstrate that the FCC may risk loss of important participation and useful data to make robust determinations if it merely assumes the significant costs of remote care delivery can be supported by HCPs or patients. The failure to consider the costs of developing and operating these programs, as well as patient outreach and the significant costs of medical devices and apps that are the lifeblood of connected care, could make the Pilot an expensive, ultimately irrelevant program.

While the Connected Care Notice asked if HCPs are able to fund the expenses of end user devices or mobile apps outside of the proposed FCC program, the consensus of the comments was that there are not other sources of funding and that this alone represents a significant obstacle to deploying remote care at scale. Ochsner provided some details in its comments on that point as did others. In addition to the concerns about the Self-Referral or Anti-Kickback Statutes and the scalability of mobile applications that Ochsner discussed, more than one third of the commenters support the inclusion of end user or medical devices as supported services in this

Pilot.[20] As one comment observed: "there can be no access to services if patients do not have the equipment needed to receive those services."[21] The Pilot would be significantly more effective if it were to provide free or discounted access to connected devices or mobile apps to underserved communities. For example, Ochsner would be able to use its "O Bar" program to help more patients set up healthcare-related mobile applications and connect health monitoring devices directly to their smartphones, allowing use of these health tools at a fraction of the cost of providing them standalone broadband connections.[22]

Further, the Connected Care Notice sought comment as to whether reimbursement under CMS guidelines, medical licensing issues or other issues create obstacles to telehealth adoption that the FCC should consider. A number of commenters identified each of these as additional obstacles. In terms of reimbursement issues, existing federal subsidy programs such as Medicare impose geographic limitations and only reimburse a relatively small, defined set of services.[23] New and innovative telehealth and connected services are usually not covered by these programs because hyper-technical eligibility requirements are imposed by these programs and they often fail to adequately anticipate technological advancement.[24] Inconsistent licensing and

[20] AdventHealth; American Association of Nurse Practitioners; American Hospital Association; Cascade Comprehensive Care; Center for Connected Health Policy; Children's Hospital of Wisconsin; CTIA; Doctor on Demand; Hathaway Sycamores; Hughes Network Systems; Lifeguard Health Networks; Medical University of South Carolina and Palmetto Care Connections; Multistakeholder; Mercy Virtual; National Consortium of Telehealth Resource Centers; OCHIN; Ochsner Health System; Partnership for Artificial Intelligence, Telemedicine, and Robotics in Healthcare; Pharmacy Health Information Technology; UnitedHealth Group; University of Mississippi Medical Center; and Virginia Telehealth Network.

[21] Comments of Viraspex at 5-6.

[22] *See* Comments of Ochsner Health System at 6-7.

[23] *See* Comments of American Hospital Association at 9.

[24] *See* Comments of Mercy Virtual at 11.

credentialing laws at state and federal levels are cited as restricting interstate mobility and cross-state practice, which in turn inhibits access to health care in underserved communities and populations.[25] The Pilot should consider this.[26] Other commenters identified lack of access to end-user devices and technology, high initial cost, interoperability of technologies, data security issues, and administrative, maintenance, training costs as additional obstacles.[27]

Ochsner recommends that the FCC work closely with CMS and other stakeholders to ensure that it is not providing funding for its Pilot program or adopting rules, processes and restrictions or preconditions that do not mesh with or are inconsistent with those of other major federal health programs addressing underserved or low-income populations. As the Comments of Americas Health Insurance Plans point out, there is variability among state Medicaid programs that also could be relevant to program design and important for the FCC to consider, as Medicaid populations could well be part of a target patient cohort for study in some Pilot proposals.[28]

Commenters who addressed the issue also generally agree that Section 254 of the Communications Act does not limit services supported by the FCC's universal service programs

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[25] *See, e.g.*, Comments of AdventHealth; Comments of American Hospital Association; Comments of American Physical Therapy Association; Comments of American Urological Association; Comments of Mercatus Center – Darcy Bryan; Comments of Partners HealthCare System; Comments of South Carolina Children's Telehealth Collaborative; and Comments of TruConnect.

[26] *See* Comments of American Physical Therapy Association at 3.

[27] *See e.g.*, Comments of American Hospital Association; Comments of Mercy Virtual; Comments of TruConnect; Comments of Telemedicine Centers USA; Comments of AdventHealth; Comments of South Carolina Children's Telehealth Collaborative; Comments of American Medical Informatics Association; Comments of American Urological Association; Comments of CoBank; Comments of Blue Cross Blue Shield Association; Comments of Mercatus Center – Darcy Bryan.

[28] *See* Comments of Americas Health Insurance Plans at 2-3.

only to broadband connections. As the Comments of the American Hospital Association state: "While it is true that the Commission has elected not to fund these items in other USF programs, more recently those decisions have been a policy choice, not a legal barrier."[29] The comments in the record have not presented evidence to the contrary. Furthermore, as commenters observed, "information services" for purposes of Section 254 encompass remote patient monitoring applications and devices with "store-and-forward" functionality.[30] In order words, there is no legal impediment to providing funding in the Pilot for medical devices provided to patients to allow remote care.

Moreover, the Connected Care Notice proposed that rather than awarding funds to those applicants selected for the Pilot, the agency would instead set a uniform discount of 85% on eligible supported services. Eligible supported services appear to include only competitively bid broadband connections that support connected care projects or trials. The Connected Care Notice asked if the proposed discount was set at the right level to incentivize wide HCP participation in a Pilot, while ensuring funds are not wasted. As Ochsner and others noted in comments, any discount on an element that is not a cost to the HCP will not provide any financial support to encourage participation in the Pilot. Rather, the costs that HCPs do incur should be considered and supported.

Therefore, Ochsner supports those commenters urging the FCC to return to a whole dollar award as opposed to applying a discount to supported services. Consistent with the FCC's original proposal in the Connected Care Notice of Inquiry, flexibility in how HCPs allocate any funding awarded is essential to providing effective connected care services to the target

[29] Comments of American Hospital Association at 21.

[30] *See also* Comments of Connected Health Initiative at 6-7; Comments of Virginia Telehealth Network at 18.

population. As one commenter stated, "[i]f budget allocations are permitted only for broadband expansion, it is unlikely Pilot projects will be able to meaningfully scale telehealth services already in place or collect and analyze process of care and outcome data."[31] Others noted that some communities may need greater financial support to establish initial infrastructure, devices, or mobile applications to connect with patients, which would not be covered by a percentage discount on broadband.[32] Many connected care programs have experienced that administrative, overhead, and associated outreach costs can vary greatly, all presenting obstacles to target populations' access to health care, especially when eligible HCPs serving target population often operate on tight margin.[33]

Finally, as many commenters noted, the Pilot should not be designed like the current FCC Rural Healthcare program that supports the costs of maintaining rural broadband among eligible healthcare facilities. Many commenters correctly observed that structuring a connected care Pilot to be similar would be a serious mistake.[34] While the FCC should not cap the number of projects it would fund at the outset, Ochsner believes that the $5 million amount the FCC previously suggested as a cap for any individual award could be enough to provide incentives to potential participation and allow more than a handful of projects to get funding. As Commissioner Rosenworcel highlighted, a Pilot program should ideally "fund projects in every

[31] Comments of Medical University of South Carolina and Palmetto Care Connections at 7; *see also* Comments of Partners HealthCare System at 1.

[32] *See* Comments of AdventHealth at 4; Comments of Cascade Comprehensive Care at 2; Comments of South Carolina Children's Telehealth Collaborative at 2-3; Comments of Virginia Telehealth Network at 8; *see also* Comments of Telemedicine Centers USA at 4.

[33] *See* Comments of Lifeguard Health Networks at 8; Comments of OCHIN at 3.

[34] *See* Comments of CTIA at 4-7; Comments of Lifeguard Health Networks at 6; Comments of TruConnect at 10; Comments of USTelecom at 2-3.

state and territory across the country."[35] Funding too few projects will not allow a sufficiently diverse pool of applicants to collect sufficient data to determine how USF funding can positively affect existing telehealth initiatives for different medical conditions, different groups of eligible patients, and in different geographical areas.

IV. Data Collection and Application Selection Factors

There were a range of comments filed on the question of whether Pilot participation should limited to HCPs or even further limited to HCPs that are located on or that serve an area with a designation as having received the Health Resources and Services Administration's (HRSA) Health Professional Shortage Area designation (HPSA), or Medically Underserved Area (MUA) designation within a defined geographic area. Most comments on this issue suggested that the FCC not screen out or reject potentially meritorious projects for failure to be entirely rural or entirely within a HRSA boundary or projects that serve mixed patient populations.[36] As Ochsner observed in its comments, weeding out projects based on setting these as initial qualification screens could prove costly in terms of the actionable information the FCC will fail to collect.

Most parties that commented on the question of whether only HCPs with clinical trial experience be considered as applicants did not believe that that should be a requirement and

[35] Connected Care Notice, 34 FCC Rcd. at 5699-700 (statement of Commissioner Jessica Rosenworcel).

[36] *See* Comments of American Academy of Family Physicians at 2; Comments of American Association of Nurse Practitioners at 3; Comments of American Medical Informatics Association at 2; Comments of Americas Essential Hospitals at 3-4; Comments of Children's Hospital of Wisconsin at 3; Comments of Geisinger at 2; Comments of Gila River Telecommunications at 4-5; Comments of Healthcare Leadership Council at 2; Comments of Lifeguard Health Networks at 12; Comments of MaineHealth at 3; Comments of Medical University of South Carolina & Palmetto Care Connections at 8; Comments of MetroHealth System at 1; Comments of Pharmacy Health Information Technology at 4; Comments of University of Mississippi Medical Center at 3; and Comments of UnitedHealth Group at 3-4.

Ochsner agrees. Certainly clinical trial experience could be useful, but none of the commenters supported the suggestion that program data be collected in a full blown clinical trial format. As several commenters appropriately observed, clinical trial protocol is not only relatively expensive, it also requires the use of control groups and administrative structures that will not add substantially to the issues the FCC seeks to study in its Pilot. [37] For some HCPs who already regularly evaluate the benefits of their connected care or telemedicine programs through other reporting metrics, the requirement to obtain a separate set of clinical trial data would be at the very least duplicative. For other HCPs (such as rural hospitals) that do not already conduct human subject research through an institutional review board, a requirement to conduct clinical trial may demand infrastructure that will further stretch their scarce resources.[38] On this point, Ochsner supports other commenters that suggested that the Pilot take advantage of already existing reporting structures in other federal programs when measuring and reporting progress and funding utilization rather than creating new forms of reporting.[39]

Certainly data collection and metrics are key to measuring success of the program and in achieving the FCC's stated goals. The Connected Care Notice suggests that participating HCPs be required to submit regular reports with anonymized, aggregated data so that each project and the overall Pilot can be evaluated. Several commenters proposed different outcome measurement indicators that do not require the collection and reporting of clinical trial data but that would still give the FCC the type of information it would need to inform public policy

[37] *See, e.g.*, Comments of American Hospital Association at 18.

[38] *See* Comments of American Hospital Association at 18; Comments of Mercy Virtual at 21-22; Comments of Netsmart at 5; Comments of OCHIN at 6; Comments of the State of Maine at 11.

[39] *See also* Comments of Connected Health Initiative at 9-10; Comments of Multistakeholder at 2.

decisions. These include: the number and demographics of patients served; patient clinical status in terms of emergency and inpatient visits, inpatient lengths of stay, site of care; condition-specific metrics; participation satisfaction and care experience; time spent by HCPs and other service providers; disease incidence and prevalence; patient/HCP technology adoption rate (enrollment or engagement); and tracking prescription refills and adherence to treatment regimens.[40] These generally seem to be appropriate and useful data for the FCC to collect.

The FCC did not get detailed comments on the Connected Care Notice questions about application ranking and selection process. As in other areas, Ochsner believes that the FCC should rank applications favorably that show experience in providing remote health programs that address chronic health conditions, as well as those that propose to serve areas or populations with well-documented health or access disparities. The selection process should, however, avoid going down a rabbit hole in determining how it would weigh a Healthcare provider Shortage area applicant versus a Medically Underserved Area applicant, for example.

[40] *See* Comments of Virginia Telehealth Network at 17; Comments of Association of State and Territorial Officials at 6; Comments of Children's Hospital of Wisconsin at 3-4; Comments of the Center for the Advancement of mHealth at 1; Comments of Medical University of South Carolina and Palmetto Care Connections at 7; Comments of OCHIN at 4.

V. Conclusion

Ochsner remains optimistic that the FCC's Pilot program can advance innovation in the provision of cost effective care to targeted populations, while making a positive difference in health outcomes. In order to learn as much as it can and then act on informed knowledge, the FCC should apply flexible guidelines for this Pilot program to encourage reasonable experimentation.

Respectfully submitted,

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